

K072441

**510(k) SUMMARY**

MAR 25 2008

**1. DATE PREPARED**

August 18, 2007

**2. SPONSOR INFORMATION**

Address

TYSON BIORESEARCH, INC.  
5 F., # 22, KE TUNG RD., SCIENCE BASED INDUSTRIAL PARK  
CHUN-NAN, MIAO-LI COUNTY, CHINA (TAIWAN) 350

Contact Person: WEN-HAI TSAI

PHONE: 886-37-585988

FACSIMILE: 886-37-585996

**3. NAME OF DEVICE:**

Trade Name:	EZ Scan Plus Blood Glucose Monitoring System
Common Names/Descriptions:	Blood Glucose Monitoring System
Classification Names:	Glucose test system, product code 75CGA and "System, test, blood glucose, over the counter", product code 75NBW, 21 CFR 862.1345

**4. DEVICE DESCRIPTION:**

The EZ Scan Plus Blood Glucose Monitoring System designed by Tyson Bioresearch Inc., an amperometric biosensor, are adopted for its ease of use, its ability to process accurate results utilizing only a small volume of blood, and its quick response time. EZ Scan Plus device provides a convenient and safe monitoring system for diabetes health care professionals, hospitals and most importantly, people with diabetes.

The EZ Scan Plus Blood Glucose Test Strips are used with the EZ Scan Plus Blood Glucose Meter to quantitatively measure glucose in capillary whole blood obtained from the fingertip and the alternate sites: palm and forearm. When the edge of the EZ Scan Plus Test Strip is touched to a drop of blood, the test strip draws the blood into the

sample chamber and the glucose reading is displayed on the meter after 10 seconds. The test measures glucose from 20 mg/dL (1.1mmol/L) to 600 mg/dL (33.3 mmol/L). The EZ Scan Plus Test Strip is calibrated to display the equivalent of plasma glucose values to allow the comparison of results with laboratory methods.

#### **5. INTENDED USE:**

The EZ Scan Plus Blood Glucose Test Strips are used with the EZ Scan Plus Blood Glucose Meter for quantitatively measuring glucose (sugar) in fresh capillary whole blood drawn from the fingertip and the alternate sites: palm and forearm. The EZ Scan Plus Test Strips are for testing outside the body (in vitro diagnostic use). The EZ Scan Plus Blood Glucose Monitoring System is intended for use at home (over the counter [OTC]) by persons with diabetes, or in clinical setting by healthcare professionals as an aid in monitoring the effectiveness of diabetes control.

#### **6. TEST PRINCIPLE**

The test principle is based on electrochemical biosensor technology using glucose oxidase. Glucose is oxidized to gluconic acid and electrons are produced from the reaction. The electrons are then trapped by a chemical mediator, potassium ferricyanide. Once the enzymatic reaction is complete, a potential is provided by the meter for a further electrochemical reaction in order to generate a current from the release of trapped electrons. This current is then measured and correlated to the glucose concentration in the whole-blood sample. The EZ Scan Plus Test Strip is calibrated to display the equivalent of plasma glucose values to allow easy comparison of results with laboratory methods.

#### **7. PREDICATE DEVICE:**

Predicate device name(s): EZ Smart - 168 Blood Glucose Monitoring System

Predicate 510(k) number(s): k052818

Comparison with predicate:

The Tyson Bioresearch Inc. EZ Scan Plus Blood Glucose Monitoring System in this submission is equivalent to the Tyson Bioresearch Inc. EZ Scan Plus Blood Glucose Monitoring System. The modification of EZ Smart-168 Blood Glucose Monitoring System. The modifications encompass the meter coding method, PCB size, meter

appearance and new indication for use (Alternate Site Testing). All main meter internal electronic components, meter functions and detection algorithm remain the same. EZ Scan Plus Test Strip is also identical to the EZ Smart-168 Test Strip, only the size changed for more convenient use. Fundamental scientific technology of the EZ Scan Plus device has not changed.

### **Substantial Equivalence Comparison:**

The Tyson Bioresearch Inc. EZ Scan Plus Blood Glucose Monitoring System in this submission is equivalent to the Tyson Bioresearch Inc. EZ Smart-168 Blood Glucose Monitoring System previously cleared under (k052818). The table below lists the similarities and differences between the Predicate and Proposed device.

#### **Similarities:**

<b>Item</b>	<b>Predicate Device EZ Smart-168 (K052818)</b>	<b>Proposed Device EZ Scan Plus</b>
Test Principle	Electrochemical biosensor with glucose oxidase.	identical
Test Strips	EZ Smart-168 Test Strip	EZ Scan Plus Test Strip
Specimen Type	Capillary whole blood	identical
Sample Volume	Around 1.5 uL	identical
Measuring Time	10 sec	identical
Detecting Range	20 ~ 600 mg/dL	identical
Unit of measurement	mg/dL or mmol/L	identical
HCT Range	35 ~55 %	identical
Operating Temperature	10 to 40 °C (50-104°F)	identical
Operating Humidity	10 to 90%	identical
Average result	28 tests average	identical
Memory capacity	28 Test Results	identical
Strip Storage Temperature	4 to 30 °C (40-86°F)	identical
Control Solution	3 Levels available	identical
Button Design	one button	identical
Battery Power	One 3 V Lithium CR 2032 battery	identical

Differences:

Item	Predicate Device EZ Smart-168 (K052818)	Proposed Device EZ Scan Plus
Intend Use	The EZ Smart-168 Blood Glucose Test Strips are used with the EZ Smart-168 Blood Glucose Meter for quantitatively measuring glucose (sugar) in fresh capillary whole blood drawn from the fingertip. Testing is done outside the body (in vitro diagnostic use). It is intended for use at home (over the counter [OTC]) by persons with diabetes, or in clinical setting by healthcare professionals as an aid in monitoring the effectiveness of diabetes control.	The EZ Scan Plus Blood Glucose Test Strips are used with the EZ Scan Plus Blood Glucose Meter for quantitatively measuring glucose (sugar) in fresh capillary whole blood drawn from the fingertip and the alternate sites: palm and forearm. Testing is done outside the body (in vitro diagnostic use). It is intended for use at home (over the counter [OTC]) by persons with diabetes, or in clinical setting by healthcare professionals as an aid in monitoring the effectiveness of diabetes control.
Blood source	fingertip	Fingertip, palm and forearm
Meter Coding	Glucose Chip	EZ Scan Plus Test Strip
Test Strips size	33.5 x 5 (mm)	33.5 x 7 (mm)
Meter Dimension	76 x 47 x 16 (mm)	102 x 52 x 17 (mm)
PCB Size	72 x 42 (mm)	92 x 44 (mm)
LCD Display	40 x 21.5 (mm)	37.5 x 34 (mm)
Meter Weight	44 grams	55 grams

## 8. PERFORMANCE CHARACTERISTIC SUMMARY

Based on the above information, we know the subject device, EZ Scan Plus Blood Glucose Monitoring System, and the predicate device have the same functioning principle and using the same technologies. The detection ranges for both devices are similar. HCT ranges are the same. The strip storage environments and the operating temperature are similar.

The differences between EZ Scan Plus from EZ Smart-168 Blood Glucose Monitoring System are the meter coding method, meter dimension, weight, PCB size and new intended use - for alternate site testing. All internal electrical architectures and main electronic components as well as product functions and features remain unchanged. EZ Scan Plus Test Strip is also identical to the EZ Smart-168 Blood Glucose Monitoring System, only the size changed for more convenient use. No physical changes of EZ Smart-168 Test Strips were made.

As we can see, the differences are due to the feature design aspects for more easy use of the EZ Scan Plus Blood Glucose Monitoring System, not relating to the safety or effectiveness aspects. Fundamental scientific technology of the EZ Scan Plus device has not changed. An evaluation of the EZ Scan Plus Blood Glucose Monitoring System was conducted under various conditions including temperature effects, humidity effects, hematocrit levels, sensitivity and linearity. The results of the evaluation demonstrate that EZ Scan Plus Blood Glucose Monitoring System is substantially equivalent to the originally cleared EZ Smart-168 Blood Glucose Monitoring System (K052818).

The results of clinical alternate site testing demonstrate that the results obtained from the alternate site sampling using EZ Scan Plus system, are similar to those obtained from finger stick whole blood with no effect on clinical action. EZ Scan Plus system provides the users an option to use the palm and forearm in addition to the fingertip to collect capillary blood for self monitoring of blood glucose within certain conditions as explained in product user' s manual. EZ Scan Plus is suitable for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Tyson BioResearch, Inc.  
c/o Mr. Wen-Hai Tsai  
5F, #22, Ke E. Road III Science-Based Industrial Park  
Chu-Nan, Miao-Li County 350  
Taiwan (ROC)

**MAR 25 2008**

Re: k072441

Trade Name: EZ Scan Plus Blood Glucose Monitoring System  
Regulation Number: 21 CFR 862.1345  
Regulation Name: Glucose Test System  
Regulatory Class: Class II  
Product Codes: NBW, CGA  
Dated: February 21, 2008  
Received: February 25, 2008

Dear Mr. Tsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

*Jean M. Cooper, M.S., D.V.M.*

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

## Indication for Use

510(k) Number (if known): K072441

Device Name: EZ Scan Plus Blood Glucose Monitoring System

Indication For Use:

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Prescription Use X  
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use X  
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol Benson  
Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

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